



Patent
Attorney's Docket No. 030662-066

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

In re Patent Application of
Keiko NERIISHI et al.
Application Serial No.: 09/749,410
Filed: December 28, 2000
For: DNA DETECTION DEVICE

) Group Art Unit: 1655

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) Examiner: A. Chakrabarti

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) Confirmation No. 5255

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REPLY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Official Action dated September 16, 2002, Applicants herein
provide the following remarks.

REMARKS

Further and favorable consideration of the subject application in light of the
following remarks are respectfully requested.

I. CLAIM STATUS & AMENDMENTS

As correctly stated in the Office Action Summary, claims 13-35 were pending in
this application when last examined.

II. REJECTIONS WITHDRAWN

A. Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1-3 under 35 U.S.C. § 112, second paragraph, has been withdrawn in view of the Amendment and Reply filed May 6, 2002. See September 16, 2002, Official Action, page 5.

B. Rejection Under 35 U.S.C. § 102(e)

The rejection of claims 1-3 under 35 U.S.C. § 102(e) for purportedly being anticipated by Some et al., U.S. Patent No. 6,256,405, has been withdrawn in view of the Amendment and Reply filed May 6, 2002. See September 16, 2002, Official Action, page 5.

C. Rejection of Claims 1-3 Under 35 U.S.C. § 103(a)

The rejection of claims 1-3 under 35 U.S.C. § 103(a) for purportedly being obvious over Some et al., U.S. Patent No. 6,256,405, in view of Linsley et al., U.S. Patent No. 6,271,002, and further in view of Ward et al., U.S. Patent No. 4,711,955, has been withdrawn in view of the Amendment and Reply filed May 6, 2002. See September 16, 2002, Official Action, page 5.

III. REJECTION UNDER 35 U.S.C. § 103(a)

Claims 1-3 stand newly rejected under 35 U.S.C. § 103(a) for purportedly being obvious over U.S. Patent No. 6,256,405 issued to Some et al. (hereinafter "Some"), in view of U.S. Patent No. 6,171,794 issued to Burchard et al. (hereinafter "Burchard").

For at least all of the reasons set forth below, Applicants respectfully traverse this rejection and request its withdrawal.

The instant rejection fails to set forth a *prima facie* case of obviousness against the claimed invention. To establish a *prima facie* case of obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. See M.P.E.P. § 2143.03; In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974); In re Zurko, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1476, 1478 (Fed. Cir. 1997); In re Wilson, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. See M.P.E.P. § 2143; In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). This element requires that an objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references to arrive at the claimed invention. In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). In other words, the Examiner must provide a logical reason as disclosed in the prior art at the time of the invention for combining the references along the lines of the invention. Otherwise, the use of such teachings as evidence of non-obviousness will entail impermissible hindsight. Ex parte Stauber, 208 U.S.P.Q. 945, 946 (Bd. App. 1980).

Third, the prior art must provide a reasonable expectation of success. See M.P.E.P. § 2143.02; Vaeck, 947 F.2d at 488, 20 U.S.P.Q.2d at 1438; In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986).

As to the first required element for establishing a *prima facie* case of obviousness, Applicants submit that the prior art fails to teach each and every element of the claimed invention for the reasons previously discussed in the May 6, 2002 Amendment and Reply and for the reasons set forth below.

Some fails to disclose, or even suggest, several key features of the claimed invention. In particular, Some does not disclose fixing **probe** DNA fragments to a micro-array and a **sample** of bringing single-stranded DNA fragments in contact therewith. Furthermore, Some does not disclose or suggest using a **spacer sheet having openings** which is placed between the DNA micro-array and the radiation image storage panel as set forth in the claimed invention. Instead, Some discloses a method for detecting complementary DNA fragments which comprises the steps of:

- (a) bringing single-stranded probe DNA fragments having a radioactive label in a liquid phase into contact with a sample DNA fixed onto a transfer support;
- (b) removing unfixed probe DNA fragments;
- (c) keeping the hybridized DNA in contact with a radiation image storage panel;
- (d) irradiating the radiation image storage panel with a stimulating light;
- (e) detecting the stimulated emission photoelectrically;
- (f) processing the electric signals to locate the area in which the complementary DNA fragments are fixed.

Some differs in several key aspects from the claimed invention. For instance, in Some, the DNA fragments to be tested are fixed to the transfer support, whereas the known probes are hybridized to the fixed DNA fragments to be tested. Some, column 7, lines 21-39. Note that the sample DNA fragments are first eletrophoresed on a gel medium and them transferred onto a transfer support according to the known Southern blotting method. This teaching clearly differs from the claimed invention. In the claimed invention, the single-stranded **probe** is fixed on a micro-array, and the radioactively labeled DNA fragment to be tested is brought into contact with the micro-array.

Furthermore, in the claimed invention, a **spacer sheet with openings**, is placed between the DNA micro-array and the radiation image storage panel in step (c). The DNA micro-array has probe compounds in predetermined areas, and thus it is easy to prepare a spacer sheet which has openings in the positions corresponding to the probe-fixed area. These openings allow for the emission of radioactive energy by the hybridized radioactively labeled DNA fragment without disturbance and noise.

Some does not disclose or suggest the use of a **spacer sheet with openings** which is placed between the DNA micro-array and the radiation image storage panel in step (c). The Examiner alleges that Some teaches an image forming method involving a process in which a spacer sheet is made of non-radiation transmitting material (column 8, lines 13-23; Figures 1 and 8, light guiding sheet in this case).

However, as fully addressed at page 5, of the May 6, 2002 Amendment and Reply, no spacer, let alone a spacer sheet with openings, is seen in figures 1 and 8. Similarly, the description in column 8, lines 13-23, of a light guiding sheet is not a description of a

spacer sheet with openings. This is further evidenced by the description in column 7, lines 43-50, which reads:

The thus obtained transfer support and the stimuable phosphor sheet 1 are placed in layers for a certain period of time to expose the stimuable phosphor sheet 1 and at least a part of radiation emitted from the radioactively labeled substance on the transfer support is absorbed in the stimuable phosphor sheet 1, whereby the locational information regarding the radioactively labeled substance in the specimen is stored in the stimuable phosphor sheet 1.

Hence, it is clear that a spacer having openings is not described in Some.

The Examiner also states at the top of page 4 of the Official Action that the spacer sheet is made of a non-radiation-transmitting material. Once again, as previously argued in the May 6, 2002 Amendment and Reply, the non-radiation-transmitting material is actually employed for the production of the light guiding sheet, which is indicated in Figures 1 and 8 by the number 8. There is no relationship between a spacer, as is used in the claimed invention, and the light guiding sheet.

It appears that the rejection is based upon a fundamental misunderstanding regarding the use of the spacer in the claimed invention. By reference to claim 1 and Figures 1 and 2, it is clear that the spacer (12) is placed between the DNA micro-array (11) and the radiation image storage panel (13) in step (c). This, however, is just not contemplated by the teachings in Some.

In summary, Some fails to disclose fixing probe DNA fragments to a micro-array and bringing single-stranded sample DNA fragments in contact therewith. Furthermore, Some does not disclose or suggest using a spacer sheet having openings which is placed between the DNA micro-array and the radiation image storage panel in step (c). Thus,

Some fails to teach or render obvious each and every element of the claimed invention.

For at least this reason, Applicants respectfully request the withdrawal of this rejection.

Burchard fails to remedy the deficiencies of Some. In this regard, Burchard also fails to disclose or suggest using a spacer sheet having openings which is placed between a DNA micro-array and a radiation image storage panel.

Therefore, with regards to the first element of a *prima facie* case of obviousness, both Some and Burchard fail to teach each and every element of the claimed invention. For these reasons alone, Applicants respectfully request the withdrawal of this rejection.

Moreover, as to the second and third elements of a *prima facie* case of obviousness, even if the disclosures of Some and Burchard were taken together, one would not arrive at the claimed invention. This is because none of these references disclose or suggest fixing probe DNA fragments to a micro-array and bringing single-stranded sample DNA fragments in contact therewith. Furthermore, none of these references disclose or suggest using a spacer sheet having openings which is placed between a DNA micro-array and a radiation image storage panel.

Therefore, in view of the above, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Finally, as to the request at page 2, of the Official Action, concerning common ownership of the subject matter of the various claims at the time the invention was made, Applicants submit that the subject matter of the various claims were commonly owned by the present Applicants at the time of the invention.

III. OTHER MATTERS

Applicants acknowledge receipt of the Notice of References Cited (*i.e.*, PTO-892).

Applicants also acknowledge receipt of the Notice of Withdrawal of Abandonment dated August 26, 2002.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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